REMARKS

This Amendment is being submitted in response to the Office Action mailed on January 14, 2008 in connection with the above-identified application.

Reconsideration of the above-identified application in view of the foregoing amendments and following remarks is respectfully requested.

STATUS OF ACTION

Claims 11-13 are currently pending and under consideration. Claims 1-10, were previously withdrawn in response to the Examiner's restriction requirement. Claim 11 has been amended to conform with proper Markush language as suggested by the Examiner. No new matter has been added as a result of these amendments.

DOUBLE PATENTING

Applicant would like to thank the Examiner for holding this rejections in abeyance until notification from the Examiner that all of the remaining rejections in connection with this application have been removed.

WITHDRAWN REJECTIONS/OBJECTIONS

Applicant would like to thank the Examiner for withdrawing the rejection of Claims 11-13 under 35 U.S.C. 102(b) as being anticipated by Chwalisz et al. (WO 01/26603).

REJECTION UNDER 35 U.S.C. SECTION 103

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeManno et al. (Steroids 2003, 68:1019-1032) in view of Chwalisz et al. (WO 01/26603), and further in view of Apgar et al. (American Family Physician: published on 10/15/2000 and retrieved online on 12/12/2007 via www.aafp.org/afg/20001015/1839.html), and further in view of Winkley, M.W. (U.S. Patent No. 5,523,427). Applicant respectfully traverses this rejection.

According to the Examiner, DeManno et al teaches that asoprinil (J867) is a selective progesterone receptor modulator, which can be used to treat gynecology disorders, i.e.

endometriosis (page 119, Introduction: 4-6). Further, the Examiner further recites that DeManno et al. teaches that treatment with asoprisnil further allows for the following:

1) induces amenorrhea (page 1031, right column, line 20-23);

2) is effective in suppressing the overproduction of uterine prostaglandin in the endometrium which is the cause for the uterine pain or dysmenorrheal (page 1031, left column, line 31-36);

3) is useful for treating various gynecological disorders, i.e. uterine fibroids, endometriosis, dysmenorrheal (uterine pain) which the treatment may induce amenorrhea (page 1031, right column, Clinical Implications: line 1-13); and

4) is effective in shrinking uterine fibroids, reducing symptoms, and suppressing both normal and abnormal uterine bleeding, i.e. menorrhagia (page 1032, left column, line 11-14).

(See page 5 of the Office Action)

The Examiner further suggests that Chwalisz et al. teaches a use of mesoprogestin, i.e. J867 or known as asoprisnil, among others, as a component for the production of pharmaceutical female contraception. Moreover, the Examiner also states that Chwalisz et al. teaches that mesoprogestin can be used sequentially with a progestin, and that when mesoprogestin is continuously administered alone, it not only suppresses the lining of the uterus and prevents nidation but also induces a reversible amenorrhea.

Moreover, the Examiner states that additional references, Apgar et al. and Winkley, teach that the progestational agent, such as, for example, medroxyprogesterone acetate or medrogestone, may be useful for producing predictable withdrawal bleeding and/or inducing and reestablishing normal menstrual cycles due to amenorrhea.

Applicant respectfully submits that each of these references specifically provide a designated use for either 1) the isolated use of a selective progesterone receptor modulator (SPRM) (i.e., DeManno), 2) the isolated use of progestin for inducing withdrawal bleeding (i.e., Apgar et al. Winkley), or 3) a sequential dosing regimen for female contraception (Chwalisz). None of these references in combination with one another suggest the presently claimed invention.

In contrast, the present invention provides a dosing regimen having a first dosing period of SPRM treatment to achieve a therapeutic effect and amenorrhea, followed by a second dosing period of progestin treatment to induce withdrawal bleeding and prevent undesirable changes in the endometrium . The regimen of the claimed invention induces a predictable return to menstruation

in order to reset the endometrium for the next course of SPRM therapy thereby protecting against the development of undesired endometrial changes. The prior art simply does not disclose or suggest such a regimen for the treatment of gynecological disorders.

As admitted by the Examiner, the DeManno et al reference specifically provides that asoprisnil may be used for gynecological therapy, such as the treatment of endometriosis, but fails to suggest the use of progestin for inducing menstrual bleeding. Moreover, each of the other relied upon references, i.e., Chwalisz et al., Apgar et al., and Winkley, suggest that the use of progestin is solely for the inducing of withdrawal bleeding following amenorrhea, but does not suggest a therapeutic effect in sequential combination with an SPRM in the treatment of any gynecological disorders. Accordingly, Applicant submits that it would not have been obvious to one of ordinary skill in the art to combine these references, since the underlying purposes of the single SPRM treatment regimen, the single progestin regimen, or the combination of the SPRM and progestin regimen were for fundamentally different purposes that do not encompass the claimed invention and there is absolutely nothing in the prior art that discloses or suggests there combination for use in treating gynecological disorders.

Although the Examiner asserts that it would have been obvious to administer a progestogen to reverse the amenorrhea cause by administration of the SPRM in the treatment of gynecological disorders, there is no suggestion by any of the references that the sequential dosage of progestin following administration of an SPRM, could be used as part of a therapeutic regimen to treatment gynecological disorders. Accordingly, Applicant suggests that the presently claimed invention would not have been obvious in view of the cited references. Therefore, in view of the aforementioned argument, this rejection is now moot and should be withdrawn.

CONCLUSION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions concerning the above, he is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

DykemaGossett PLLC
10 South Wacker Drive, Suite 2300
Chicago, Illinois 60606 USA
(312) 876-1700
(312) 627-2302 (facsimile)
www.dykema.com
ipmail@dykema.com

Respectfully submitted,

/ Lisa V. Mueller/
Attorney for Applicant
Reg. No. 38,978

Date: May 10, 2008

Direct telephone calls to: 312-627-2184

AMENDMENTSPRM\4.3
ID\